



Don J. Mizerk  
Attorney  
120 South Riverside Plaza, Suite 2200  
Chicago, IL 60606-3912  
312.526.1546  
fax: 312.655.1501  
don.mizerk@huschblackwell.com

August 6, 2009

**Via Email with Confirmation via U.S. Mail**

Amanda J. Tessar  
Gibson, Dunn & Crutcher LLP  
1801 California Street, Suite 4200  
Denver, CO 80202-2642

Arthur Makadon  
Edward Rogers  
Susanna Greenberg  
BALLARD SPAHR ANDREWS &  
INGERSOLL, LLP  
51st Floor  
1735 Market Street  
Philadelphia, PA 19103

Joseph F. Roda  
Dianne M. Nast (DMN 1791)  
Erin C. Burns  
RODANAST, P.C.  
801 Estelle Drive  
Lancaster, PA 17601

Daniel J. Boland  
Thomas E. Zemaitis  
Pepper Hamilton, LLP  
3000 Two Logan Square  
Eighteenth & Arch Streets  
Philadelphia, PA 19103

John M. Desmarais  
Michael P. Stadnick  
KIRKLAND & ELLIS LLP  
Citigroup Center  
153 East 53rd Street  
New York, NY 10022

Re: *In re: Wellbutrin XL Antitrust Litigation*, Case No. 2:08-cv-2431 (E.D. Penn.); and  
*Biovail Laboratories, Inc. v. Anchen Pharmaceuticals, Inc.*, Case No. 04-cv-01468 (C.D.  
Cal.)

Dear Counsel:

I write on behalf of Anchen Pharmaceuticals ("Anchen") and am responding to an email I received this morning from counsel for the Biovail defendants. I have enclosed a copy of this email hereto for your reference.

As you know, Anchen was a defendant in one of the underlying cases involving efforts to market a generic version of Wellbutrin XL. We were advised by counsel for Biovail that certain

Counsel in *In re: Wellbutrin XL Antitrust Litigation*  
August 6, 2009  
Page 2

Anchen confidential documents and information that are in the possession of Biovail from the underlying litigation and subject to a protective order issued therein have been requested by Plaintiffs in the above-referenced antitrust litigation. The email I received this morning suggests that Anchen's position has not been accurately presented to Plaintiffs' counsel or the Court in the antitrust litigation.

By letter dated July 20, 2009, Anchen advised Biovail's counsel that it had no objection to the production of such information subject to the entry of a suitable protective order. In the letter, Anchen explained that the parties' proposed order did not adequately protect Anchen's legitimate interests. A copy of that letter is attached for your reference. Anchen made a number of specific requests and changes to the proposed order to address its concerns. As the letter explained, most of Anchen's comments and concerns were not directed at the Plaintiffs in the antitrust litigation, but at the Defendants, who are competitors of Anchen and are attempting to obtain access to confidential Anchen information in the antitrust matter on terms far more permissive than those allowed by the district court in the underlying litigation. This is not acceptable to Anchen. Protection of Anchen confidential information was the subject of several rather contentious motions and hearings leading to the entry of several court orders and opinions, the most recent of which was attached to my July 20, 2009 letter.

To date, we have received no response to this letter, or the concerns addressed therein, *at all*. Despite having heard nothing in response to our request for a protective order, we understand that Plaintiffs are preparing a motion to compel that relates at least in part to the dissemination of Anchen's confidential information. This seems to be contrary to the applicable "meet and confer" requirements and the protections in the rules to the imposition of unnecessary expenses on third parties. Should Anchen be required to incur costs in connection with this matter or any motion filed by the parties, we will seek costs pursuant to Federal Rule of Civil Procedure 37(a)(5). Anchen has requested limited and specific protections in an effort to avoid any unnecessary expense or motion practice and they have been completely ignored by the parties to the litigation.

Again, Anchen has stated that disclosure can proceed subject to a suitable protective order and no one has objected to the terms that Anchen has requested, or stated any reason why they cannot be accommodated. Therefore, motion practice is not necessary and disclosure should proceed along the terms that Anchen has proposed.

Counsel in *In re: Wellbutrin XL Antitrust Litigation*  
August 6, 2009  
Page 3

Please do not hesitate to contact me if you have any questions. In the event that the parties proceed with a motion despite the facts and current posture of this issue, we would request that the Court be provided with a copy of this letter and all of its attachments.

Sincerely,

HUSCH BLACKWELL SANDERS LLP  
WELSH & KATZ

A handwritten signature in black ink, appearing to read "Don J. Mizerk", with a stylized, cursive script.

Don J. Mizerk

DJM/ch  
Attachments

**Mizerk, Don**

---

**From:** Tessar, Amanda J. [ATessar@gibsondunn.com]  
**Sent:** Thursday, August 06, 2009 7:18 AM  
**To:** Hoefler, Carol; Mizerk, Don  
**Cc:** Merrill, Kourtney Mueller; Royall, M. Sean; Drake, Monique M.  
**Subject:** RE: Biovail Laboratories, Inc. v. Anchen Pharmaceuticals, Inc.

Dear Don,

Thank you for your letter. To date, Biovail has not produced any Anchen confidential information to the antitrust plaintiffs in *In re Wellbutrin XL Antitrust Litigation*, Case Nos. 08-CV-2431, -2433 (E.D. Pa.). Biovail objected to doing so based on the terms of the protective order from the *Anchen* litigation and also based on our understanding that Anchen does not consent to the production of its confidential materials to the antitrust plaintiffs under the terms of the protective order governing the antitrust litigation.

Judge McLaughlin conducted the Rule 16 conference for the antitrust case on Tuesday. The antitrust plaintiffs complained about the fact that Biovail has objected to production of Anchen's confidential information. Judge McLaughlin reviewed Paragraph 15 of the *Anchen* protective order and suggested that the antitrust plaintiffs file a motion to compel, which would then trigger Anchen's opportunity to secure confidential treatment of its materials in the context of the antitrust litigation. Judge McLaughlin indicated that, once she has the plaintiffs' motion in hand, she will issue an order permitting Anchen to present arguments regarding the use of its confidential information in the antitrust litigation.

The plaintiffs stated that they intend to file their motion to compel on Monday, August 10. Under the local rules, assuming an August 10 filing date, responses are ordinarily then due on August 24, 2009, although Judge McLaughlin hinted that she might impose a different deadline in these circumstances.

We asked the plaintiffs to serve Anchen with its motion, but will also forward it to you directly at this email address when we receive it.

Please let me know if you have any questions.

--Amanda

Amanda Tessar  
Gibson, Dunn & Crutcher LLP  
1801 California St., Suite 4200  
Denver, CO 80202  
Telephone: (303) 298-5742  
Fax: (303) 313-2826

---

**From:** Hoefler, Carol [mailto:Carol.Hoefler@huschblackwell.com]  
**Sent:** Monday, July 20, 2009 3:51 PM  
**To:** Tessar, Amanda J.  
**Cc:** Mizerk, Don  
**Subject:** Biovail Laboratories, Inc. v. Anchen Pharmaceuticals, Inc.

Please see the attached correspondence sent on behalf of Don Mizerk. If you have difficulty opening the attachment, please contact me. Thank you.

**IB DISCOURAGED**

8/6/2009

**Carol A. Hoefler**  
**Legal Administrative Assistant**  
Husch Blackwell Sanders Welsh & Katz  
120 South Riverside Plaza, Suite 2200  
Chicago, IL 60606  
Direct Phone: 312.985.8221  
Direct Fax: 312.655.1501  
E-Mail: [carol.hoefler@huschblackwell.com](mailto:carol.hoefler@huschblackwell.com)  
Website: [www.huschblackwell.com](http://www.huschblackwell.com)

\*\*\*CONFIDENTIAL ATTORNEY-CLIENT COMMUNICATION FROM HUSCH BLACKWELL SANDERS LLP WELSH & KATZ\*\*\*

This email message and all attachments, if any, may contain confidential and privileged material and are intended only for the intended recipient. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email or by calling (312) 985-8221 and destroy the original and any copies of this email.

=====  
This message may contain confidential and privileged information. If it has  
been sent to you in error, please reply to advise the sender of the error and  
then immediately delete this message.  
=====

8/6/2009



Don J. Mizerk  
Attorney  
120 South Riverside Plaza, Suite 2200  
Chicago, IL 60606-3912  
312.526.1546  
fax: 312.655.1501  
don.mizerk@huschblackwell.com

July 20, 2009

**Via Email with Confirmation via U.S. Mail**

Amanda J. Tessar  
Gibson, Dunn & Crutcher LLP  
1801 California Street, Suite 4200  
Denver, Colorado 80202-2642

Re: *Biovail Laboratories, Inc. v. Anchen Pharmaceuticals, Inc.*  
-Case No. 04-cv-01468 (C.D. Cal.)

Dear Ms. Tessar:

I am writing in response to your letter dated June 22, 2009, regarding materials subject to the protective order entered in the above-referenced case. Please note that my firm and contact information have changed.

As you know, it was Anchen's position that Biovail's counsel was required to return or destroy most of Anchen's designated materials shortly after the appeal in the matter was concluded. Without prejudicing our rights, we agreed to allow you limited access to the items that counsel mostly likely would have been allowed under the terms of the protective order to retain for a limited purpose, still subject to the terms of the protective order. That said, we understand that the parties to the antitrust litigation would request access to some of this information and we are amenable to attempting to work out some sort of agreement that allows the antitrust parties access to certain information, while protecting Anchen's continued interest in the confidentiality of its proprietary information.

First, we agree that the Court's order in the underlying litigation does not allow you to disclose Anchen confidential information without Anchen approval. No Anchen confidential information should be provided in the antitrust case until a protective order acceptable to Anchen is in place. The draft protective order you have provided to us does not adequately protect Anchen's information. It does not seem to address the present facts in which a party is in possession of materials that have been designated as confidential by a non-party to the litigation. The draft protective order is deficient in a number of respects:

1. The proposed order allows expanded access to Anchen confidential information to in-house Biovail personnel under conditions more liberal than those provided in the existing protective order. As an initial matter, we do not see any need for any non-lawyer at Biovail or GSK to be given access to Anchen confidential information. In addition, any in-house lawyer at Biovail or GSK must agree to execute a declaration consistent with the district court's opinion in

Amanda J. Tessar  
July 20, 2009  
Page 2

*Biovail v. Anchen*, No. 04-cv-68, slip op. at 13 (C.D. Cal. Nov. 22, 2006) (copy attached). For example, in the enclosed *Biovail* case, the district court refused to allow Biovail's general counsel access to Anchen's confidential information if she was unwilling to sign a declaration that stated in substance as follows:

None of my positions at Biovail have involved participation in competitive decision-making activities. I have not played any role in Biovail's decisions concerning the pricing, sales, design, or development of its products. I have not been involved in the filing or prosecution of patent applications. I have not been involved in the preparation of substantive submissions to the FDA concerning NDA No. 21-515 (Wellbutrin XL) and/or Citizens' Petitions relating to ANDAs referencing NDA No. 21-515. In my present position as Senior Counsel, I have no role in competitive decision-making. My offices, which are located in downtown Toronto, Canada, are entirely separate from the offices of Biovail Corporation, which are located in Mississauga, a suburb of Toronto.

In fact, the Court called Anchen's request "eminently reasonable." *Id.* at 15. Given the parties' history and experience, we cannot allow Anchen's proprietary information to be disseminated internally at Biovail or GSK without careful controls. *See Biovail v. Anchen*, No. 04-cv-68, slip op. at 13 ("[I]t is indisputable that [the relevant portions of Anchen's ANDA] are trade secrets, the disclosure of which to a competitor ... (or the public) would be extremely damaging to Anchen's interests.").

2. To the extent that information will be provided to additional persons, such as outside experts, Anchen must be given advance notice of the disclosure with a reasonable opportunity to evaluate the request. Paragraph 6 of the proposed order does not appear to require such notice because Anchen would not be the "producing party." This problem is repeated throughout the draft order, including paragraphs 17, 18, and 26.

3. The parties to the case, also, should not have the ability to dedesignate Anchen confidential information produced by Biovail. Paragraphs 13 and 21 of the draft order appear to allow the parties to the litigation change confidentiality designations without approval from Anchen.

4. We also have concerns about paragraph 15 of the draft order. This provision would appear to allow the parties to the antitrust case to use Anchen confidential information without restriction in public court hearings. This is not acceptable to Anchen. We believe that the parties should not be allowed to use Anchen information in any public proceeding without prior notice to and permission from Anchen.



Amanda J. Tessar  
July 20, 2009  
Page 3

5. Paragraph 22 of the draft order also appears to allow Biovail to disclose Anchen confidential materials from the underlying litigation without restriction. I do not think that this was the intent, but the paragraph does not appear to address the present situation in which Biovail (and possibly GSK) are in possession of Anchen's confidential information and would be producing it in the antitrust matter.

Second, Anchen would like to have the opportunity to review certain documents containing its confidential information prior to their production so that it can move for a protective order if it sees any problem. We do not need to review in advance pleadings, discovery responses, expert reports, deposition transcripts or correspondence with Anchen from the underlying litigation. We also understand that there is a request for a "log, list or index" of other documents produced, including documents produced by Anchen. I did not see any request for anything else that would contain Anchen confidential information, but if anything else is going to be provided, we would like a chance to review it and seek a protective order prior to production if we think there is a reason to further limit the production.

Please let me know if you have any questions or how you would like to proceed in addressing the issues outlined above.

Sincerely,

HUSCH BLACKWELL SANDERS LLP  
WELSH & KATZ

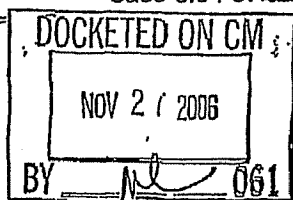


Don J. Mizerk

Attachment  
DJM/ch



Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 1 of 16



UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES--GENERAL

Priority  
Send  
Enter  
Closed  
JS-5/JS-6  
JS-2/JS-3  
Scan Only

Case No. SACV 04-1468-JVS(RCx).

Date: November 22, 2006

Title: Biovail Laboratories, Inc. v. Anchen Pharmaceuticals, Inc.

=====

DOCKET ENTRY

=====

HON. ROSALYN M. CHAPMAN, UNITED STATES MAGISTRATE JUDGE

Marsha Eugene-Domingue  
Deputy Clerk

None  
Court Reporter

453-454  
Tape No.

ATTORNEYS PRESENT FOR PLAINTIFF:  
Michael G. Ermer  
Thomas G. Slater, Jr.  
Robert W. Loftin

ATTORNEYS PRESENT FOR DEFENDANT:  
Donald J. Mizerk  
Stacey N. Knox  
John B. Sganga, Jr.

PROCEEDINGS: (1) ORDER DENYING DEFENDANT ANCHEN PHARMACEUTICALS, INC.'S MOTION TO ENFORCE THE PROTECTIVE ORDER AND FOR SANCTIONS; AND (2) ORDER DENYING PLAINTIFF BIOVAIL LABORATORIES, INC.'S MOTION TO MODIFY THE PROTECTIVE ORDER

On October 30, 2006, plaintiff Biovail Laboratories, Inc. ("Biovail"), and defendant Anchen Pharmaceuticals, Inc. ("Anchen"), filed a joint stipulation presenting two motions: (1) Anchen's motion to enforce the protective order against Biovail (or for a finding of contempt) and for sanctions; and (2) Biovail's motion to modify the protective order; Biovail also filed the supporting declarations of Scott D. Baskin, Michael G. Ermer, Thomas G. Slater, Jr., and Jill R. Sperber and an evidentiary appendix, and Anchen also filed the supporting declaration of Don J. Mizerk with exhibits; on October 31, 2006, Biovail filed a memorandum questioning this Court's jurisdiction to hear Anchen's motion to enforce the protective order; and on November 8, 2006, both Biovail and Anchen filed supplemental memoranda and Anchen filed a response to Biovail's memorandum questioning this Court's jurisdiction.

Oral argument was held on November 22, 2006, before Magistrate Judge Rosalyn M. Chapman. Biovail was represented by Michael G. Ermer, attorney-at-law with the firm Irell & Manella, and Thomas G. Slater, Jr., and Robert W. Loftin, attorneys-at-law

#229

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 2 of 16

with the firm Hunton & Williams, and Anchen was represented by Donald J. Mizerk and Stacey N. Knox, attorneys-at-law with the firm Winston & Strawn and John B. Sganga, Jr., attorney-at-law with the firm Knobbe Martens Olson & Bear.

**BACKGROUND**

On July 20, 2005, this Court signed a stipulated Protective Order ("Protective Order"), which provides, in pertinent part:

\* \* \*

3. The parties may obtain confidential treatment, as defined in this Order, for such documents by typing or stamping "Confidential" (or words of similar import) on each page or to the front cover of the electronic version of the documents for which confidential treatment is desired. Pages so designated shall hereinafter be referred to as "Confidential Documents." Any Confidential Document or confidential information contained therein shall be used solely for the purpose of preparing for and conducting pretrial and trial proceedings in this action where counsel agree to be bound by the terms of this protective order. *Nothing in this Order prevents a party from applying to the Court for permission to use confidential information in other court or agency proceedings. . . .*

\* \* \*

6. Documents or portions thereof may be designated "Confidential" pursuant to the terms of this Order:

- (a) If the portion of the document discloses proprietary and confidential trade secrets or confidential research, development or commercial information, the disclosure of which to competitors, customers or employees, would cause substantial harm to current legitimate business interests, or discloses information invasive of the legitimate privacy interests of individuals (for example, private medical information of subjects in a clinical study); or
- (b) if the Court shall rule such documents to be Confidential after appropriate notice and for good cause shown.

\* \* \*

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 3 of 16

9. Except by prior Court Order or with the prior written consent of the designated party, documents and transcripts designated as "Confidential" hereunder (and the Confidential information contained therein) shall be disclosed only to the following persons:

SECRET

- (a) the Court and its official personnel, provided that such Confidential documents shall be filed under seal pursuant to the procedures set forth in L.R. 79-5.1[;]
- (b) personnel of any of the outside law firms of record representing any of the parties to this action to the extent necessary to provide representation to the party in connection with this action; court reporters, translators, third-party photocopy or imaging services contractors, third-party contractors producing graphic or visual aids solely in providing litigation support services to outside counsel;
- (c) any person of whom sworn testimony is taken, except that such person may not retain any such materials;
- (d) jury consultants involved solely in providing litigation support services to outside counsel;
- (e) independent experts (i.e., an individual not an employee or otherwise an agent of a party, who is retained or consulted by counsel solely for the purpose of assisting in this action), but only after following [the notice and objection] procedures set forth in paragraph 11 below; and
- (f) any other person permitted to receive confidential information by order of the Court or by written agreement of the Parties. The parties agree that Kenneth Cancellara and Dina Khairo of Biovail Corporation are qualified under this section to review confidential information pursuant to this Order.

\* \* \*

14. At the conclusion of this litigation (including all appeals), all documents or transcripts designated "Confidential" and any copies thereof, shall either be

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 4 of 16

returned to the producing party, or counsel shall certify to the destruction of said documents. *This Order shall continue to be binding after the conclusion of this litigation, except that there shall be no restriction on documents or transcripts that are (a) used as exhibits and/or offered into evidence not under seal in the pretrial activities or trial of this action, and (b) not covered by any subsequent and inclusive confidentiality order.*

STEWART

\* \* \*

20. This Order may be modified, amended or vacated by further order of the Court upon the motion of any party for good cause shown.

Protective Order (emphasis added).

On July 19, 2006, District Judge James V. Selna denied the parties' joint request to close to the public the hearing scheduled on the parties' cross-motions for summary judgment, stating "[t]he grant or denial of summary judgment is a matter of public concern[.]" and on July 24, 2006, Judge Selna held the public summary judgment hearing. At the hearing, both parties made slide show presentations of some evidence they had submitted under seal with their cross-motions for summary judgment. Declaration of Michael G. Ermer, ¶¶ 6-7, Exh. 3; Declaration of Scott D. Baskin, ¶¶ 5-8; Declaration of Jill R. Sperber, ¶¶ 5-8. The slides were projected "on a large screen that could be viewed by the Court, [the parties'] counsel, and the individuals in the gallery."<sup>1</sup> Baskin Decl., ¶¶ 5, 7; Sperber Decl., ¶¶ 5, 7. Nevertheless, Anchen did not object to any of the exhibits or request to seal the exhibits or the record of the summary judgment hearing. Ermer Decl., ¶ 5, Exh. 3; Baskin Decl., ¶ 9; Sperber Decl., ¶ 9. One of the 18 or so slides presented by Biovail included the document that is the focus of Anchen's motion to enforce the Protective Order or for a finding of contempt against Biovail -- part of Anchen's generic Abbreviated

<sup>1</sup> Individuals in the gallery included members of the public. Baskin Decl., ¶ 4; Sperber Decl., ¶ 4. At oral argument, Biovail noted that following the public summary judgment hearing, at least two journalists reported the financial implications of Judge Selna's tentative ruling and information presented at the hearing.

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 5 of 16

New Drug Application ("ANDA") for bupropion hydrochloride extended release tablets entitled Section VII 1.b "Components & Compositions for 300 mg. Tablets" (hereafter "ANDA Section VII 1.b document").<sup>2</sup> Ermer Decl., ¶¶ 5-6, Exh. 3 at 103:2-6, Exh. at 165; Baskin Decl., ¶ 6; Sperber Decl., ¶ 6. Previously, Anchen had designated ANDA Section VII 1.b document as confidential, and it was filed under seal as part of Anchen's motion for summary judgment. Declaration of Don J. Mizerk, ¶ 16(7), Exh. 7.

On August 1, 2006, Judge Selna denied Biovail's motion for partial summary judgment on its patent infringement claim and granted Anchen's motion for summary judgment on its counterclaim for patent noninfringement, specifically finding Anchen's generic ANDA for bupropion hydrochloride extended release tablets does not infringe Biovail's '341 patent, and on August 25, 2006, Judgment was entered in favor of Anchen. At the same time, Judge Selna ordered the Court to retain "continuing jurisdiction to enforce the Stipulated Protective Order in this action and to preside over issues concerning the Stipulated Protective Order." On September 13, 2006, Biovail filed a notice of appeal to the Federal Circuit Court of Appeals.

On August 27, 2006, Biovail, through its attorney John B. Dubeck, submitted the following correspondence to the Food and Drug Administration ("FDA") regarding Anchen's generic ANDA for bupropion hydrochloride extended release tablets:

On July 24, 2006 for the first time the formulation of Anchen Pharmaceutical, Inc.'s drug product alleged to be bioequivalent to the branded drug Wellbutrin XL was made public. During the course of a public summary judgment hearing held in the open courtroom of Judge James V. Selna in the United States District Court for the Central District of California, Anchen's drug product was shown to have the a [sic] structure wherein a core tablet containing bupropion hydrochloride (the active ingredient) is surrounded by a number of

<sup>2</sup> The slides Anchen presented at the public summary judgment hearing also included portions of Anchen's ANDA. Ermer Decl., ¶¶ 5, 7, Exh. 3 at 65:4-98:6, 119:1-125:9; Baskin Decl., ¶¶ 7-8, Exh. 5 at 228; Sperber Decl., ¶¶ 7-8, Exh. 5 at 228.

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 6 of 16

coatings. . . . [¶] The important issue raised by the formulation is the absence of a plasticizer from any of the coating formulations. . . . Without a plasticizer in the delayed release coating, Anchen's formulation deviates very significantly from manufacturer's instructions. . . .

SCANNED

\* \* \*

In the instant case there are additional reasons for alarm. Seizures are dose dependent adverse event[s] associated with bupropion hydrochloride. The labeling recommends titrating patients slowly to minimize that risk. Accordingly, dose dumping for bupropion poses particularly serious risks to patients. The accelerated dose release that is likely to result from the coating design deficiencies noted above will be amplified if the product is consumed with a solvent more aggressive than water. . . . [¶] Until the information relating to Anchen's formulation was made public in late July, Biovail had no way of knowing anything about Anchen's formulation. Even within the context of the patent infringement litigation, all of the information relating to the formulation and its performance is confidential and is the subject of a protective order that severely limits access to this information. Biovail hopes to obtain an exemption from the terms of the protective order so that it can review and report additional information to the [FDA] that may have escaped its attention. . . .

Mizerk Decl., ¶ 16(7), Exh. 7 (emphasis added). ANDA Section VII 1.b document was attached as an exhibit to Mr. Dubeck's letter.  
Id.

#### DISCUSSION

##### I

Anchen now seeks an order finding Biovail has violated the Protective Order by giving ANDA Section VII 1.b document to Mr. Dubeck, whom the parties agree is not authorized to receive such confidential information under the Protective Order, and Anchen also seeks an award of monetary sanctions against Biovail for its

//



contumacious conduct.<sup>3</sup> As a preliminary matter, Biovail claims this Court (Magistrate Judge Chapman) does not have jurisdiction to decide a motion for contempt. However, Biovail is in error. Under 28 U.S.C. § 636(e), this Court has the power to "exercise contempt authority" by, *inter alia*, determining whether an act by a party or nonparty constitutes "a civil contempt" and, if so, by "certify[ing] the facts to a district judge . . . [and] requiring [the contemnor] to appear before a district judge upon a day certain to show cause why that person should not be adjudged in contempt by reason of the facts so certified." 28 U.S.C. § 636(e)(6). Thus, Anchen's motion to enforce the Protective Order is properly before this Court.

"It is well-established that the fruits of pretrial discovery are, in the absence of a court order to the contrary, presumptively public." San Jose Mercury News, Inc. v. U.S. Dist. Court-N. Dist., 187 F.3d 1096, 1103 (9th Cir. 1999); Phillips v. General Motors Corp., 307 F.3d 1206, 1210 (9th Cir. 2002). Rule 26(c), which governs the granting of a protective order,<sup>4</sup>

<sup>3</sup> Additionally, Anchen requests the Court require Biovail: (a) to provide sworn statements identifying all individuals other than counsel of record and disclosed experts who have been provided confidential information and identifying all disclosures and use of the confidential information other than in this litigation; (b) to exclude any person or firm that received confidential information in violation of the Protective Order from continuing to participate in any court proceeding, FDA matter or patent prosecution relating to Wellbutrin XL and/or ANDA's referencing Wellbutrin XL; and (c) to require all confidential information be returned to Anchen's trial counsel immediately and to restrict further access of confidential information solely to a reasonable number of outside attorneys, who are handling the appeal in this matter. See Jt. Stip. at 17:1-18:23 & n.6.

<sup>4</sup> A protective order should be granted when the moving party establishes "good cause" for the order and "justice requires [a protective order] to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense. . . ." Fed. R. Civ. P. 26(c). "For good cause to exist, the party seeking protection bears the burden of showing specific prejudice or harm will result if no protective order is granted." Phillips, 307 F.3d at 1210-11; Beckman Indus., Inc. v. Int'l Ins. Co., 966 F.2d 470, 476 (9th Cir.), cert. denied, 506



"authorizes a district court to override this presumption where 'good cause' is shown." San Jose Mercury News, Inc., 187 F.3d at 1103. Moreover, a district court retains the power to modify or vacate protective orders it has entered. Empire Blue Cross & Blue Shield v. Janet Greeson's A Place For Us, Inc., 62 F.3d 1217, 1219 (9th Cir. 1995); Beckman Indus., Inc., 966 F.2d at 473.

The Protective Order in this case allows a party or nonparty producing a document to initially determine whether such document is confidential, without court intervention. As such, the Protective Order is a "blanket" protective order, which is "inherently subject to challenge and modification, as the party resisting disclosure generally has not made a particularized showing of good cause with respect to any individual document." San Jose Mercury News, Inc., 187 F.3d at 1103; Beckman Indus., Inc., 966 F.2d at 476; see also Kamakana v. City and County of Honolulu, 447 F.3d 1172, 1183 (9th Cir. 2006) (The "confidential categorization of discovery documents under the protective order was not a guarantee of confidentiality, especially in the event of a court filing. Although the magistrate judge 'expressly approved and entered the protective order,' the order contained no good cause findings as to specific documents that would justify reliance. . . ."); Foltz v. State Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1133 (9th Cir. 2003) ("[A] party seeking the protection of the court via a blanket protective order typically does not make the 'good cause' showing required by Rule 26(c) with respect to any particular document. Thus, reliance on a blanket protective order in granting discovery and settling a case, without more, will not justify a refusal to modify.").

"The standard for finding a party in civil contempt is well settled: The moving party has the burden of showing by clear and convincing evidence that the contemnors violated a specific and definite order of the court." In re Dyer, 322 F.3d 1178, 1190-91 (9th Cir. 2003) (citation omitted); Federal Trade Comm'n v. Enforma Natural Prods., Inc., 362 F.3d 1204, 1211 (9th Cir. 2004).<sup>5</sup> "The burden then shifts to the contemnors to

---

U.S. 868 (1992).

<sup>5</sup> "To distinguish civil from criminal contempt, the focus of the inquiry is often 'not [upon] the fact of the punishment but rather its character and purpose.'" Falstaff Brewing Corp.

demonstrate why they were unable to comply.'" Enforma Natural Prods., Inc., 362 F.3d at 1211 (citations omitted); In re Bennett, 298 F.3d 1059, 1069 (9th Cir. 2002). "The contempt 'need not be willful,' and there is no good faith exception to the requirement of obedience to a court order"; rather, a party may be held in civil contempt when it fails "to take all reasonable steps within the party's power to comply" with the court's order. Go-Video, Inc. v. Motion Picture Ass'n of America, 10 F.3d 693, 695 (9th Cir. 1993) (citation omitted); Reno Air Racing Ass'n v. McCord, 452 F.3d 1126, 1130 (9th Cir. 2006). "[H]owever, a person should not be held in contempt if his action 'appears to be based on a good faith and reasonable interpretation of the court's order.'" Reno Air Racing Ass'n, 452 F.3d at 1130 (citation omitted); Go-Video, Inc., 10 F.3d at 695. Further, "[s]ubstantial compliance' with the court order is a defense to civil contempt, and is not vitiated by 'a few technical violations' where every reasonable effort has been made to comply. Go-Video, Inc., 10 F.3d at 695 (citations omitted); Hallett v. Morgan, 296 F.3d 732, 750 (9th Cir. 2002).

As an initial matter, the Court notes with disappointment that Biovail did not "apply[] to the Court for permission to use confidential information" before the FDA, as permitted by paragraph 3 of the Protective Order. Nevertheless, Biovail's failure to obtain permission from the Court to submit ANDA Section VII 1.b document to the FDA is not a violation of the Protective Order. Rather, paragraph 14 of the Protective Order specifically states, in part: "[T]here shall be no restriction on documents or transcripts that are (a) used as exhibits and/or offered into evidence not under seal in the pretrial activities or trial of this action. . . ." Protective Order ¶ 14 (emphasis

---

v. Miller Brewing Co., 702 F.2d 770, 778 (9th Cir. 1983) (citations omitted); Shillitani v. United States, 384 U.S. 364, 369, 86 S. Ct. 1531, 1534, 16 L. Ed. 2d 622 (1966). "The primary purpose of criminal contempt is to punish past defiance of a court's judicial authority, thereby vindicating the court. . . ." Falstaff, 702 F.2d at 778; Shillitani, 384 U.S. at 370, 86 S. Ct. at 1535. "Civil contempt is characterized by the court's desire to compel obedience to a court order, or to compensate the contemnor's adversary for the injuries which result from the noncompliance." Falstaff Brewing Corp., 702 F.2d at 778 (citation omitted); In re Heritage Bond Litigation, 223 F.R.D. 527, 531 (C.D. Cal. 2004).

added). The combined phrase "and/or" is, at best, ambiguous. See, e.g., In re Swaffar, 253 B.R. 441, 448 (E.D. Ark. 2000) ("The 'civil and/or criminal contempt' phrase is not only confusing, but ambiguous as well."). Similarly, whether the phrase "not under seal" modifies only "offered into evidence" or both "used as exhibits" and "offered into evidence" is also ambiguous. Nevertheless, this Court need not resolve these ambiguities since the Court finds Biovail's interpretation of paragraph 14 of the Protective Order to be reasonable. Specifically, Biovail interprets paragraph 14 to exclude from confidentiality protection ANDA Section VII 1.b document because it was "used as [an] exhibit[] and/or offered into evidence not under seal" during the public hearing on the parties' cross-motions for summary judgment. This is a reasonable interpretation of the Protective Order. Here, the record clearly shows that ANDA Section VII 1.b document was presented as an exhibit in open court by Biovail to support its argument for partial summary judgment, without Anchen objecting to the exhibit or requesting to seal it or the record. Thus, Anchen has not shown by clear and convincing evidence that Biovail's disclosure of ANDA Section VII 1.b document to either Mr. Dubeck or the FDA is a violation of the Protective Order or that Anchen has acted contumaciously.<sup>6</sup> Reno Air Racing Ass'n, 452 F.3d at 1130 (citation omitted); Go-Video, Inc., 10 F.3d at 695; see also Imageware, Inc. v. U.S. West Commc'ns, 219 F.3d 793, 797 (8th Cir. 2000) ("No one should be held in contempt for violating an ambiguous order, especially an order purporting to restrict the right of the public to see public records and documents. A contempt should be clear and certain.").

Further, even if paragraph 14 of the Protective Order did not provide that documents "used as exhibits and/or offered into evidence not under seal in . . . pretrial activities" are excluded from its confidentiality protection, public policy requires that exclusion. See, e.g., Littlejohn v. BIC Corp., 851 F.2d 673, 680 (3d Cir. 1988) ("It is well established that the release of information in open court 'is a publication of that

---

<sup>6</sup> At oral argument, Biovail represented to the Court that it would not distribute to Mr. Dubeck or any other unauthorized person any of the other exhibits that were publically disclosed at the hearing on the parties' cross-motions for summary judgment until final resolution by the district court of Anchen's motion to enforce the Protective Order against Biovail.

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 11 of 16

information and, if no effort is made to limit its disclosure, operates as a waiver of any rights a party had to restrict its future use.' The references to the confidential documents made in open court may have constituted a sufficient publication. But, in any event, we hold that BIC's failure to object to the admission into evidence of the documents, absent a sealing of the record, constituted a waiver of whatever confidentiality interests might have been preserved under the [protective order]." (citations omitted)); Nat'l Polymer Products, Inc. v. Borg-Warner Corp., 641 F.2d 418, 421 (6th Cir. 1981) ("[It is a] well-established principle of American jurisprudence that the release of information in open trial is a publication of that information and, if no effort is made to limit its disclosure, operates as a waiver of any rights a party had to restrict its further use."); Rambus, Inc. v. Infineon Technologies AG, 2005 WL 1081337, \*3 (E.D. Va. 2005) ("[T]he previous public use effectively stripped the documents of any protection under the protection order."); Zenith Radio Corp. v. Matsushita Electric Ind. Co., Ltd., 529 F. Supp. 866, 898-99 (E.D. Pa. 1981) ("[P]ortions of documents that are read into the record in an open proceeding enter the public domain, without regard to whether the documents were originally filed on the public record, were filed under seal, or were not filed with the clerk."). Thus, Anchen's motion for a finding that Biovail violated the Protective Order or for contempt and sanctions against Biovail should be DENIED.<sup>7</sup>

## II

During the course of this litigation, Anchen produced approximately 9,000 "confidential" documents, including its generic ANDA and amendments thereto, lab notebooks, analytical requests, and test results documenting Anchen's research and development efforts, and an FDA communication regarding Anchen's generic ANDA. Mizerk Decl., ¶ 15. Biovail now seeks to modify the Protective Order to allow: (1) unidentified attorneys and consultants to review Anchen's confidential documents and to comment on the information in those documents to the FDA;<sup>8</sup> and

<sup>7</sup> As such, this Court need not address Biovail's other arguments regarding the propriety of civil contempt in this matter.

<sup>8</sup> At oral argument, Biovail identified the following people as the attorneys and consultants it seeks permission to allow to

Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 12 of 16

(2) Biovail's new general counsel, Wendy Kelley, to review Anchen's confidential documents so she can perform her job duties. Biovail represents that "[a]ll of the individuals to whom such 'confidential' information would be disclosed are willing to be subject to the restrictions of the Protective Order so that the information would only be used for communications with the FDA[,] and not publically disseminated or provided to Anchen's other competitors. *Jt. Stip.* at 44:16-21 (emphasis added). Needless to say, Anchen vehemently opposes Biovail's motion.

Although the Protective Order is "inherently subject to challenge and modification" since the parties, and Anchen in particular, never "made a particularized showing of good cause with respect to any individual document[,]" San Jose Mercury News, Inc., 187 F.3d at 1103; Beckman Indus., Inc., 966 F.2d at 476, Biovail's motion is without merit. Here, Biovail has not identified the specific documents it seeks to have released from protection, but broadly refers to all documents attached to the parties' cross-motions for summary judgment, and that is not good enough. *Cf. SmithKline Beecham Corp. v. Synthron Pharm. Ltd.*, 210 F.R.D. 163, 168 (M.D. N.C. 2002) ("[T]he wholesale release of documents creates problems when doing so impinges on a wide variety of confidentiality, from trade secrets to less confidential business information. The burden of reviewing such a wholesale request constitutes grounds for denying the same."); Doctor's Hosp. of Jefferson, Inc. v. Southeast Med. Alliance, Inc., 878 F. Supp. 884, 886 (E.D. La. 1995) (denying motion to modify protective order when "plaintiff seeks modification of a protective order which it freely entered into without specifically identifying documents which it believes do not fall within the scope of the Protective Order").

Nevertheless, Biovail relies on "the strong presumption of access to judicial records[, which] applies fully to dispositive pleadings, including motions for summary judgment and related attachments." Kamakana, 447 F.3d at 1179 (citations omitted); Foltz, 331 F.3d at 1135-36. Thus, "compelling reasons" must be

---

review the confidential documents: Attorneys Wendy Kelley (Anchen's new general counsel), John Dubeck (FDA counsel), Ronald Rauschenberg, Kevin Perra, and Frederick Stein; and consultants Linda Felton, Paul Maes, and Arnold Beckett.



shown to seal judicial records attached to a dispositive motion, -- even exhibits previously filed under seal or a protective order. Kamakana, 447 F.3d at 1179; Foltz, 331 F.3d at 1136. "[A]lthough the common law right creates a strong presumption in favor of access, the presumption can be overcome by sufficiently important countervailing interests." San Jose Mercury News, 187 F.3d at 1102; Kamakana, 447 F.3d at 1179. In general, "compelling reasons" sufficient to outweigh the public's interest in disclosure and justify sealing court records exist when such 'court files might have become a vehicle for improper purposes,' such as the use of records to gratify private spite, promote public scandal, circulate libelous statements, or release trade secrets." Kamakana, 447 F.3d at 1179 (citations omitted; emphasis added); Nixon v. Warner Commun., Inc., 435 U.S. 589, 598, 98 S. Ct. 1306, 1312, 55 L. Ed. 2d 570 (1978).

Here, Anchen submitted most of its generic ANDA and amendments thereto as sealed exhibits to its motion for summary judgment, and it is indisputable that these documents are trade secrets, the disclosure of which to a competitor such as Biovail (or the public) would be extremely damaging to Anchen's interests. Kamakana, 447 F.3d at 1179; see also Appleton v. Food & Drug Admin., 451 F. Supp. 2d 129, 141 (D. D.C. 2006) ("[D]ocuments contain[ing] information consisting of drug product manufacturing information, including manufacturing processes or drug chemical composition and specifications" constitute trade secrets and the "[r]elease of this information would reveal how the drug being discussed in the document 'is formulated, chemically composed, manufactured, and quality controlled[.]'" (citations omitted)); Andrx Pharm., LLC v. GlaxoSmithKline, PLC, 236 F.R.D. 583, 586 (S.D. Fla. 2006) ("Courts dress technical information with a heavy cloak of judicial protection because of the threat of serious economic injury to the discloser of scientific information." (citation omitted)), affirmed by, 2006 WL 2403942 (S.D. Fla.); Citizens Comm'n on Human Rights v. Food & Drug Admin., 1993 WL 1610471, \*7 (C.D. Cal. 1993) (A drug application to FDA "by definition contains trade secret information because it contains significant information about how a . . . drug product is formulated, chemically composed, manufactured, and quality controlled."), aff'd in part & remanded in part on other grounds, 45 F.3d 1325 (9th Cir. 1995). Indeed, in making representations to this Court for issuance of the Protective Order, both parties represented that documents containing trade secrets that need confidentiality protection

would be produced during discovery. See Protective Order at 2:4-17; see also Serono Labs., Inc. v. Shalala, 35 F. Supp. 2d 1, 21 (D. D.C. 1999) ("In a field as competitive and technical as the pharmaceutical industry, success or failure will turn in large measure on innovation and the members of the industry justifiably hoard their trade secrets as jealously as a miser hoards his gold.").

Nevertheless, Biovail argues that its correspondence with the FDA is akin to "collateral litigation" and, as such, this Court should modify the Protective Order to allow its designated attorneys and consultants to review Anchen's generic ANDA and the amendments thereto so they can comment about these documents to the FDA, while still enforcing the Protective Order against the general public. See, e.g., Jt. Stip. at 49:14-25. However, even assuming *arguendo* the unlikely proposition that Biovail's correspondence with the FDA can be considered "collateral litigation" and modification of protective orders is favored in collateral litigation, Foltz, 331 F.3d at 1131-32, such considerations are inapposite here, where granting Biovail's request would be tantamount to circumventing the FDA's policies and procedures. See, e.g., In re Gabapentin Litigation, 312 F. Supp. 2d 653, 667 n.7 (D. N.J. 2004) ("ANDAs are confidential under federal law. 21 C.F.R. § 314.430(b)-(d). It stands to reason that [intervenor] should not be able to gain access to that information through a court case arising out of an ANDA filing when it could not obtain the information in the ANDA filing directly."); Serono Labs., 35 F. Supp. 2d at 3-4 ("Ferring is perfectly correct in insisting that the agency in this case must purge the administrative record of Ferring's trade secrets before it files the administrative record for review by any one else and that a protective order restricting access to those secrets cannot excuse the FDA from fulfilling its statutory obligation to protect Ferring's trade secrets. Simply put, the protective order cannot relieve FDA from a statutory obligation it has to Ferring and permit it to abrogate a statutory right Ferring can assert."). Since Biovail's motion appears to be an improper attempt to circumvent the FDA's policies and regulations, Biovail is not entitled to a modification of the Protective Order. See, e.g., AT&T Corp. v. Sprint Corp., 407 F.3d 560, 562 (2d Cir. 2005) ("Drizin's motion appears to be an attempt to circumvent the close of discovery in his State Court Action. Thus, he is not entitled to a modification of the Protective Order." (citation omitted)); Wright, Miller & Marcus,



Federal Practice & Procedure: Civil 2d § 2044.1 (2d ed. 1994) ("If the limitation on discovery in the collateral litigation would be substantially subverted by allowing access to discovery material under a protective order, the court should be inclined to deny modification."). In other words, since the FDA is now considering Anchen's generic ANDA, and it does not make those documents available to Anchen's competitors for review and comment, see Serono Labs., Inc., 35 F. Supp. 2d at 2 ("Congress has required the FDA to guard the trade secrets to which it has been given access and . . . return them to the company which generated them."), neither should this Court. Accordingly, Biovail's motion to modify the Protective Order to allow additional attorneys and consultants to review Anchen's confidential documents so Biovail can comment upon these documents to the FDA should be **DENIED**.<sup>9</sup>

Finally, the Court must consider whether Biovail's new general counsel, Wendy Kelley, may review Anchen's confidential documents without executing a declaration stating she would not be involved in competitive decision-making at Biovail, as her predecessor had done. See Jt. Stip. at 45:4-7; Mizerk Decl., ¶ 16(16), Exh. 16. However, Biovail has not fully explained why Ms. Kelley needs access to Anchen's confidential documents, what confidential documents she needs to review, and how Anchen can be protected from disclosure of its trade secrets to a competitive decision-making person like Ms. Kelley. In other words, it appears to the Court that Anchen's opposition to Ms. Kelley reviewing its confidential trade secrets unless she executes a declaration regarding her specific job duties and role in competitive decision-making by Biovail is eminently reasonable. Thus, Biovail's motion to modify the Protective Order to allow review of confidential documents by Ms. Kelley also should be **DENIED**. See Brown Bag Software v. Symantec Corp., 960 F.2d 1465, 1471-72 (9th Cir.) (affirming protective order limiting newly hired in-house counsel's access to other party's trade secrets), cert. denied, 506 U.S. 869 (1992); U.S. Steel Corp. v. United States, 730 F.2d 1465, 1467 (Fed. Cir. 1984) ("In a particular case, e.g., where in-house counsel are involved in competitive decision-making, it may well be that a party seeking access

---

<sup>9</sup> Nevertheless, nothing prevents Biovail from commenting to the FDA on Anchen's generic ANDA by filing a citizen's petition, which Biovail has already done.

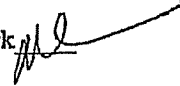
Case 8:04-cv-01468-JVS-RC Document 279 Filed 11/22/2006 Page 16 of 16

should be forced to retain outside counsel or be denied the access recognized as needed."); Andrx Pharm., LLC, 236 F.R.D. at 586-87 (denying in-house counsel who actively engages in competitive decision-making access to other party's confidential information); Intel Corp. v. VIA Tech., Inc., 198 F.R.D. 525, 527-32 (N.D. Cal. 2000) (in-house counsel's need for access to all information learned through discovery to direct litigation is insufficient to modify protective order when in-house counsel is engaged in competitive decision-making and represents an unacceptable risk of inadvertent disclosure).

#### ORDER

1. Defendant Anchen Pharmaceuticals, Inc.'s motion to enforce the Protective Order and for sanctions against Biovail Laboratories, Inc. **IS DENIED.**
2. Plaintiff Biovail Laboratories, Inc.'s motion to modify the Protective Order **IS DENIED.**
3. Pursuant to Rule 11 of the Federal Circuit Rules, any further requests to modify the Protective Order should be made to the Federal Circuit Court of Appeals. See Fed. Cir. R. 11(e) ("A party may move at any time in this court to modify a protective order to remove protection from some material or to include another person within its terms. This court may decide the motion or may remand the case to the trial court.").

2: 00

Initials of Deputy Clerk 

case041\04-1468.7  
11/27/06

I HEREBY CERTIFY THAT THIS DOCUMENT WAS SERVED  
BY FAX DELIVERY ON PLAINTIFF/DEFENDANT (OR PARTIES)  
AT THEIR RESPECTIVE MOST RECENT FAX NUMBER OF RECORD  
IN THIS ACTION ON THIS DATE.

DATE: 11/27/06

  
DEPUTY CLERK